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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/738,938	12/17/2003	Raul G. Barletta	801204-0003	8745

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EXAMINER	
RAMIREZ, DELIA M	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/738,938	BARLETTA ET AL.	
	Examiner	Art Unit	
	Delia M. Ramirez	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Claims 1-23 are pending.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, 4-5, 7-10, drawn to a recombinant mycobacterium comprising the recombinant plasmid pBUN250, classified in class 435, subclass 253.1.

II. Claims 3, 6, 11-12, drawn to a recombinant mycobacterium comprising the recombinant plasmid pBUN276, classified in class 435, subclass 253.1.

III. Claims 13-14, drawn to a *M. smegmatis* D-alanine ligase, classified in class 435, subclass 183.

IV. Claim 15, drawn to a *M. tuberculosis* D-alanine ligase, classified in class 435, subclass 183.

V. Claims 16-17, drawn in part to a method for screening for inhibitors of D-alanine ligase or inhibitors which target the D-alanine branch of mycobacterial peptidoglycan synthesis, wherein said method requires incubation of a recombinant mycobacterium comprising the recombinant plasmid pBUN250, classified in class 435, subclass 32.

VI. Claims 16-17, drawn in part to a method for screening for inhibitors of D-alanine ligase or inhibitors which target the D-alanine branch of mycobacterial peptidoglycan synthesis, wherein said method requires incubation of a recombinant mycobacterium comprising the recombinant plasmid pBUN276, classified in class 435, subclass 32.

VII. Claims 18-21, drawn in part to a method for assaying *M. smegmatis* D-alanine ligase activity or a method for screening for drugs which target the D-alanine branch of

mycobacterial peptidoglycan synthesis that requires assaying *M. smegmatis* D-alanine ligase activity, classified in class 435, subclass 4.

VIII. Claims 18-21, drawn in part to a method for assaying *M. tuberculosis* D-alanine ligase activity or a method for screening for drugs which target the D-alanine branch of mycobacterial peptidoglycan synthesis that requires assaying *M. tuberculosis* D-alanine ligase activity, classified in class 435, subclass 4.

IX. Claim 22, drawn to a method for analyzing the mechanism of action of antimycobacterial drugs by analyzing the free amino acid pool, classified in class 436, subclass 90.

X. Claim 23, drawn to a vaccine composition comprising a live-attenuated recombinant mycobacterium strain, classified in class 424, subclass 248.1.

The inventions are distinct, each from the other because of the following reasons:

2. Groups I-IV, X each comprise a chemically unrelated structure capable of separate manufacture, use, and effect. The recombinant mycobacteria of Groups I-II are living organisms, the proteins of Groups III-IV comprise amino acids, and the vaccine composition of Group X comprises adjuvants in addition to live-attenuated recombinant mycobacteria. The recombinant mycobacteria of Groups I-II has other uses besides the production of the proteins of Groups III-IV, such as to produce endogenous metabolites. Furthermore, the proteins of Groups III-IV can be produced by processes which are materially different from recombinant expression in the mycobacteria of Groups I-II, such as by chemical synthesis, or by isolation from natural sources. The proteins of Groups III-IV each comprise an unrelated amino acid sequence. The recombinant mycobacteria of Groups I-II each comprise an unrelated plasmid. The vaccine composition of Group X, while comprising live-attenuated recombinant mycobacteria, requires additional components such as adjuvants, which would enhance the immune response against the antigen. These additional components are not required in the products of Groups I-II.

3. Inventions I-II and V-IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the recombinant mycobacteria of Inventions I-II can be used in the methods of Inventions V-IX as well as in the vaccine composition of Invention X.

4. Inventions III-IV and VII-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins of Inventions III-IV can be used in the methods of Inventions VII-VIII as well as to elicit antibodies.

5. Inventions V-IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the vaccine composition of Invention X is neither used nor made by the methods of Inventions V-IX.

6. Inventions III-IV and V-VI, IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the proteins of Inventions III-IV are neither used nor made by the methods of Inventions V-VI, IX.

7. Inventions V-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of inventions V-IX comprise different steps, may use different products, and produce different results.

8. As set forth in MPEP § 803, the criteria for a proper restriction between patentably distinct inventions requires that the inventions must be independent or distinct as claimed, and a search of all the inventions would impose a serious burden on the examiner. Groups I-X have been shown to be independent or distinct, for the reasons set forth above. MPEP § 803 also indicates that a serious burden on the examiner may be prima facie shown if the Examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search. The inventions of Groups I-X have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification. In addition, a search of all the inventions would require at a minimum a separate patented/non-patented literature search and a class/subclass search. These searches are not all co-extensive. Therefore a comprehensive examination of all groups would impose an undue burden on the Examiner. Thus, restriction for examination purposes as indicated is proper.

9. The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

10. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and

process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

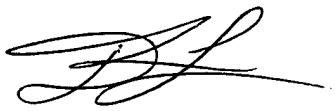
11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement can be traversed (37 CFR 1.143).

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally

be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
June 24, 2006